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Investment in medical technology, high or low tech, is integral to our ability to achieve health and development objectives worldwide. Over the last 20 or so years, the U.S. Agency for International Development (USAID) has developed, adapted, and introduced many affordable health products, policies, and practices appropriate for addressing health-related concerns in developing countries. USAID's support ranges from proof of principle and field testing to introduction at scale.

USAID's support for new technologies in health, nutrition, and family planning has involved commercial organizations, attracted co-funding from other donors, and partnered with a host of non-governmental organizations (NGOs), universities, research organizations, and local groups.

USAID's investments have led to products that now reach millions, saving lives throughout the developing world. USAID past and future products include safe injection technologies like auto-

disable syringes and vaccine vial monitors; diagnostic tests for anemia, vitamin A deficiency, and malaria; long lasting insecticide-treated nets, point-of-use water disinfectants and other products that today are used in countries throughout the developing world. More recently, USAID has supported significant advances in the use of telemedicine to reach health workers and increase the capacity of countries to meet their health needs.

AUTO-DISABLE SYRINGES

Surveys in developing countries have shown that 30 to 50 percent of injections are not sterile. Disposable syringes are reused, and reusable syringes often are improperly sterilized. At the same time, multi-dose vials often lead to 50 percent of vaccine being wasted and/or children being turned away because health workers are reluctant to open a vial for just one child.

In 1987, a decade before the international public health community mobilized around the problem of frequent reuse of contaminated needles and syringes, USAID identified the need for technologies that could prevent reuse. Working with Program for Appropriate Technology in Health (PATH) through the USAID-supported HealthTech program, USAID launched a program to develop and introduce the devices now known as auto-disable (AD) syringes.

By the early 1990s, two suitable AD technologies had been developed, evaluated in the field, licensed to a major syringe manufacturer, and produced in pilot quantities. One of them – the Soloshot™ syringe – was one of the first feasible approaches to nonreusable syringes for

immunizations. USAID funded the first validation tests of the device in Pakistan under the direct observation of the World Health Organization (WHO). These successful field trials led to scale-up, production, and introduction of the first commercial AD syringe for immunizing children. In 1996, 56 million AD syringes were distributed by UNICEF, primarily for immunization campaigns; distribution had increased to 150 million by 1999.

Alternative AD syringe designs became available in the latter half of the 1990s, encouraged and facilitated by USAID and its partners. AD syringes now improve the safety of routine immunizations as well as a growing number of curative procedures. Since their commercial introduction in 1992, more than 1 billion SoloShot syringes have been supplied to public health programs in more than 40 countries in Africa, Asia, Eastern Europe, and Latin America. UNICEF now provides only AD syringes (many of them Soloshot) to countries requesting disposable syringes. In 2005, USAID- and CDC-funded projects supplied 12 of the 15 PEPFAR focus countries in Africa and the Caribbean with more than 15 million safety syringes for use in curative care.

USAID also supported another version of the AD syringe, the Uniject™¹ injection device. Uniject is a unique pre-filled, single-use syringe with a needle attached. The device was invented and developed with USAID funding. In collaboration with the licensee, Becton, Dickinson and Company, the world's largest manufacturer of injection equipment, USAID and PATH carried out all the steps of product development and field trials.

¹ Uniject is a trade mark

BD now commercially produces and distributes the device to drug and vaccine manufacturers.

The Uniject device cannot be reused. Traditional birth attendants (TBAs) can use it to immunize hard-to-reach children and women in their communities. Multidose vial waste is eliminated, saving precious dollars. Indonesia now provides the birth dose of hepatitis B (HB) vaccine in the Uniject device to all infants born in the country. UNICEF has identified Uniject as an important tool in its efforts to eliminate maternal and neonatal tetanus in high-risk areas around the world. By allowing TBAs to deliver safe injections, Uniject is especially effective in reaching women who have not been immunized due to ethnic or religious barriers or limited health infrastructure.

The Uniject also has a role to play in the health of mothers. Hemorrhage is the leading cause of maternal mortality, and is a particular problem in home deliveries because the short response time makes referral impractical in most cases. Annually, approximately 130,000 women are known to die due to hemorrhage during childbirth. The use of oxytocin for routine management of the third stage of labor can significantly reduce the incidence of postpartum hemorrhage. Active management of the third stage of labor includes routine use of a 10 IU dose of oxytocin given intramuscularly and is recommended by the World Health Organization for all institutional deliveries and home deliveries attended by a person with midwifery skills.

A prefilled, nonreusable syringe is thought to be the safest mechanism for delivering the life-saving benefits of oxytocin to women in peripheral health care settings and homes. This prefilled, easy-to-use, injection-ready format assures that an accurate pre-measured dose is given in a nonreusable, sterile device with minimal preparation and minimum waste. These benefits may greatly improve the ability of midwives and village health workers to administer oxytocin as part of the Active Management of Third Stage of Labor to the large numbers of women giving birth outside clinic or hospital settings. Oxytocin filled Uniject devices may also be ideal for use in emergency situations and remote locations. USAID is working to make this technological promise a reality.

The World Health Organization (WHO) estimates that 85% of newborn deaths are due to infections—sepsis and tetanus make up a significant portion of these infections. Of the 12 countries in which most of the world’s neonatal tetanus occurs, six are African. In 2000, a WHO advisory committee developed a document for the “management of the child with a serious infection or severe malnutrition.” In this document, WHO recommended intramuscular injections of ampicillin and gentamicin as the standard therapy for these bacterial infections and the treatment of neonatal septicemia, meningitis, and pneumonia.

In order to achieve maximum impact on neonatal sepsis rates, it is important that newborns with these infections receive immediate treatment, even before the infectious agent is known. USAID is supporting the Uniject[™] devices pre-filled with a single injectable gentamicin dose. These

Uniject[™] is a trademark of BD.

devices could be easily transported and used in a home setting with an oral antibiotic. Community health workers and traditional birth attendants could be trained to use gentamicin-Uniject and a complementary oral antibiotic to extend the accessibility and facilitate the administration of antibiotics for early treatment of neonatal infections before referral. Gentamicin-Uniject can provide a platform to enable health workers to provide an immediate dose that would be inconvenient or impossible with standard needle and syringe.

The use of AD syringes increases the volume of medical waste in the form of used syringes and needles. Infectious sharps waste is dangerous to health care workers, waste handlers, and the community. Safe disposal methods for sharps are needed to protect anyone who may come in contact with contaminated needles.

USAID supports the development and advancement of technologies that health workers can use to safely dispose of used needles and syringes. These include safety boxes and needle removers to safely separate the used and possibly contaminated needles from the syringe for easier disposal. USAID-supported waste technologies currently are being used in the PEPFAR focus countries in conjunction with AD syringes. Needle removers already are in wide use in immunization programs, and WHO has included needle removal as a safe disposal option in health care waste management plans for sub-Saharan Africa.

VACCINE VIAL MONITORS

USAID has been involved in developing technologies to improve vaccine quality by limiting the adverse effects of excessive heat and freezing. Vaccines require careful storage and transport to the point of use to avoid harmful heat exposure or freezing temperatures. When there was no way to detect whether individual vials had been exposed to heat during storage or transport, national immunization programs had very conservative guidelines for vaccine handling and disposal of vaccines.

In 1987, USAID launched a search for suitable technologies that could identify exposure to heat. The result the “vaccine vial monitor” (VVM), a small circular indicator printed directly on vial labels or fastened to the tops that changes color irreversibly from light to dark with exposure to heat over time.

Since their introduction in 1996, VVMs have helped ensure that only potent vaccine is used to immunize children. The presence of VVMs made it possible for the polio eradication campaign to carry oral polio vaccine safely into remote areas without refrigeration. It enabled WHO to implement a multidose vial policy that allows health workers to use opened vials of vaccine for more than one day. Since January 2001, UNICEF has required that all its vaccines have VVMs. To date, more than 1 billion vaccine vials with VVMs have been delivered to developing countries. Over the next ten years vaccine vial monitors will allow health workers to recognize and replace more than 230 million doses of inactive vaccine and to deliver 1.4 billion more doses in remote settings—actions that could save more than 140,000 lives and reduce morbidity for countless others.

Other technological solutions to constraints on immunization programs that USAID has under development include needle-free jet-injector devices that can be used for giving injections without needles and thermostable vaccines that will not require refrigeration.

MALARIA

USAID supported CDC to conduct a series of scientific trials that proved that insecticide treated nets were an effective tool to prevent infant and child deaths from malaria. The Agency, in partnership with CDC, is now working to get the nets distributed to the most vulnerable populations throughout Africa.

TUBERCULOSIS

The ancient scourge of tuberculosis (TB) remains a public health threat with almost 9 million new cases each year. The internationally recommended “DOTS” strategy for managing TB cases has been accepted nearly worldwide, and its use has increased considerably in the last five years. Yet, only 53% of estimated TB cases are detected and benefit from this therapeutic intervention.

The DOTS strategy is the best proven line of defense against tuberculosis. However, it relies on a 100-year old diagnostic technology, a drug regimen whose newest addition came 40 years ago, and labor-intensive case management of the 6-8 month treatment. The only vaccine available for TB, BCG, was introduced in 1921 and offers protection against severe forms of disease in children under 5 but offers minimal protection to adults.

Almost half of TB cases remain undetected, largely due to barriers to access to appropriate diagnosis and care. The “Global Plan to Stop TB 2006-2015” and the new Stop TB Strategy proposed by WHO mainstream innovations in service delivery such as DOTS-plus for drug-resistant disease, algorithmic approaches to screening for TB, public-private partnerships for implementing TB control, coordinated management of TB/HIV and revised treatment regimens that only five years ago were topics of research. USAID was a key donor for the research behind many of these advances.

USAID’s current plan for TB calls for supporting research to optimize the effectiveness of existing technologies while continuing its support for late-stage clinical trials of new drugs and diagnostics. USAID also is ramping up efforts to prepare the field for the introduction of new technologies and to address barriers to access to services. By 2009, USAID will be responding to a robust pipeline of potential new diagnostics by supporting field trials and testing novel approaches to deliver these new tools at country-level.

RAPID DIAGNOSTICS FOR VITAMIN A DEFICIENCY, ANEMIA, AND MALARIA

USAID has field tested a relatively simple, rapid, and inexpensive enzyme immunoassay for use in assessing the prevalence of vitamin A deficiency in populations and the effects of program interventions. This test uses technology that is already established in many district- and provincial-level hospitals and laboratories, thus making it much more practical than the

current method of measuring vitamin A deficiency. (Test's name is Retinol-binding Protein Assayt)

For anemia, the Hemocue test consists of drawing a tiny amount of blood from a simple finger prick into a disposable cuvette and inserting it into a small, battery-operated device. Seconds later, an accurate reading of an individual's hemoglobin level is available. The results of Hemocue tests, which cost less than \$1 per test, are guiding interventions and monitoring progress in addressing anemia, which affects more than one-third of the world's population, especially young children and women.

Malaria rapid diagnostic tests (MRDTs) are new products that could significantly improve the diagnosis of malaria in developing countries, especially where microscopic diagnosis is not available. Some experts estimate that 35–60 percent of malaria in Africa is wrongly diagnosed. The benefits of a sensitive, specific, quick, simple, and inexpensive diagnostic test for malaria are considerable and could be used in settings where resources are limited and more sophisticated testing equipment may not be available.

TELEMEDICINE

USAID supports advances in medical technology to improve the level of care to critically ill patients in underserved international communities through long-distance medicine, or "telemedicine" technology. Through Medical Missions for Children (MMC), USAID established a system of internet video conferencing that allows volunteer doctors from 30 mentoring hospitals in the United States to examine, diagnose, and treat sick children

abroad. Through use of an extensive videoconferencing network, remote, critically ill children can be treated through specialized one-on-one care through live, two-way diagnostic and treatment consultations between specialists based at major U.S. medical centers and physicians in local hospitals.

In 2003, USAID's Global Development Alliance invested \$1 million in efforts to expand the telemedicine network throughout Latin America and the Caribbean. Satellite ground stations were built in Bolivia, Brazil, Guatemala, Mexico, and Panama to allow remote communities in these countries to receive medical education programming. The ground stations can store and forward up to 120 hours of medical content for on-demand access at each of the five USAID hospital sites.

Global communications technology company Intelsat Ltd. donated satellite bandwidth to help establish the technology infrastructure and add an education component in addition to real-time examination, diagnosis, and treatment. Polycom, a leading video conferencing company, provided video communications equipment to expand the MMC Global Telemedicine & Learning Network.

Today a network of nearly 600 doctors volunteer a minimum of 12 hours per year to help hospitals in developing countries better diagnose and treat patients. Doctors' pro-bono consultancies, in-kind contributions of equipment, and other donor support augment USAID's investment by at least four times.

In South Africa USAID is funding \$3 million as part of the federal government's Emergency Plan for AIDS Relief and will use the funding to expand South Africa's public health education channel. The Health Channel will be a satellite broadcast channel to deliver free education to patients and healthcare workers in clinics and hospitals in South Africa. The channel was created through a public private partnership between the Department of Health, Sentech, and Mindset Network. The Mindset Health Channel aims to be in all 4,000 public healthcare sites in South Africa within 5 years, serving 97,000 nurses and 36 million South Africans.

Eventually, the channel has the potential to be extended across all of Africa and will create a sustainable, mass-scale public health intervention tackling all major health issues. The network, also available through digital video online to qualified medical professionals, functions like an on-air educational symposium.